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Dated: February 16, 2010 Signature: /Jeanne M. Brashear/56,301
(Jeanne M. Brashear)

Docket No.: 31265/5868A
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Xin Lu et al.

Patent No.: 7,645,859

Confirmation No.: 1608

Issued: January 12, 2010

Art Unit: 1642

For: TUMOUR SUPPRESSOR PROTEIN

Examiner: M. T. B. Davis

**APPLICATION FOR PATENT TERM
ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

Patentees request that the U.S. Patent and Trademark Office (PTO) reconsider its calculation of Patent Term Adjustment (PTA) for the above-referenced application. This request is timely filed within two months of the issuance of the patent on January 12, 2010.

The correct PTA will be in excess of the 70 days of PTA indicated on the cover page of the Patent due to the PTO's failure to issue the patent within three years of pendency and the PTO's miscalculation of "Applicant Delay".

I. INTRODUCTION

"A Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO responses. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than a three year application pendency.

II. PATENTEES DO NOT DISPUTE THE PTO'S CALCULATION OF "A DELAY" FOR THE PRESENT APPLICATION

Patentees do not dispute, for purposes of this request, the PTO's calculation of Patent Office delay of 69 days under 35 U.S.C. § 154(b)(1)(A).

III. THE PTO MISCALCULATED "B DELAY" TO THE DETRIMENT OF THE PATENTEES

The PTO did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). The PTO accorded no PTA for "B Delay." To arrive at this conclusion, the PTO may have measured application pendency from February 20, 2007, the date on which the application fulfilled the requirements of 35 U.S.C. § 371. However, the governing statutes and regulations require that when calculating "B Delay" for a national stage filing under 35 U.S.C. § 371, application pendency must be measured from the date that is 30 months from the priority date of the international application -- not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371, if such date occurred later. As explained in detail below, the relevant 30 month date is June 10, 2006.

A. Authorities that define "B Delay"

The statute provides, in relevant part, that the term of a patent shall be extended if the PTO fails to issue a patent within three years after the "actual filing date" of the application:

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States ... the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.
35 U.S.C. § 154(b)(1)(B). (emphasis added)

The PTO's governing rule explains the meaning of the term "actual filing date" as used in 35 U.S.C. § 154(b)(1)(B). As detailed below, PTO delay for a

national stage application begins if the PTO fails to issue a patent within three years after the date the national stage “commenced under 35 U.S.C. 371(b) or (f).”¹

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application, but not including... .

37 C.F.R. § 1.702(b). (emphasis added)

35 U.S.C. §§ 371(b) and (f) refer to the time when a national stage application “commences”:

(b) Subject to subsection (1) of this section, the national stage shall commence with the expiration of the applicable time limit under article 22 (1) or (2), or under article 39 (1)(a) of the treaty. (emphasis added)

(f) At the express request of the applicant, the national stage of processing may be commenced at any time at which the application is in order for such purpose and the applicable requirements of subsection (c) of this section have been complied with.

Section 371(f) relates to international applications for which an applicant files an express request for early processing, not applicable to this case. Absent such a request, the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b), i.e., with the expiration of the applicable time limit under article 22(1) or (2), or under article 39(1)(a) of the treaty. The term “the treaty” refers to “the Patent Cooperation Treaty done at Washington, on June 19, 1970.” See 35 U.S.C. § 351(a).

“The applicable time limit” referred to in Patent Cooperation Treaty articles 22(1), 22(2), and 39(1)(a) is “the expiration of 30 months from the priority date.” As a result, “the expiration of 30 months from the priority date” is the time at which the U.S. national stage commences under the provisions of 35 U.S.C. § 371(b). See also MPEP § 1893.01:

¹ Consistent with 37 C.F.R. § 1.702(b), MPEP § 2730 states that [i]n the case of an international application, the phrase ‘actual filing date of the application in the United States’ [as used in 35 U.S.C. § 154(b)(1)(B)] means the date the national stage commenced under 35 U.S.C. 371 (b) or (f).”

Subject to 35 U.S.C. 371(f), commencement of the national stage occurs upon expiration of the applicable time limit under PCT Article 22(1) or (2), or under PCT Article 39(1)(a). See 35 U.S.C. 371(b) and 37 CFR 1.491(a). PCT Articles 22(1), 22(2), and 39(1)(a) provide for a time limit of not later than the expiration of 30 months from the priority date. Thus, in the absence of an express request for early processing of an international application under 35 U.S.C. 371(1) and compliance with the conditions provided therein, the U.S. national stage will commence upon expiration of 30 months from the priority date of the international application. Pursuant to 35 U.S.C. 371(f), the national stage may commence earlier than 30 months from the priority date, provided applicant makes an express request for early processing and has complied with the applicable requirements under 35 U.S.C. 371(c).

MPEP § 1893.01. (emphasis added)

Thus, the “actual filing date” of a U.S. national stage application filed under 35 U.S.C. § 371, for purposes of calculating “B Delay” under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is the date that is 30 months from the priority date of the international application.

B. Proper calculation of “B Delay” for the eventual patent based on the present application.

The present application is a § 371 national stage filing of International Application No. PCT/GB2004/003492, filed August 13, 2004, which claims priority benefit of Great Britain Application No. 0328690.3, filed December 10, 2003, and U.S. Provisional Application No. 60/554,990, filed March 19, 2004.

The national stage for the present application “commenced” under the provisions of 35 U.S.C. § 371(b), 30 months from the priority date of the international application,² on June 10, 2006 (30 months from the priority date of December 10, 2003).

The correct measure of “B Delay” by the PTO is measured from June 11, 2009 to January 12, 2010, inclusive. See 37 C.F.R. §§ 1.702(b) and 1.703(b). That period is **216 days**.

The PTO’s calculation of PTA made no provision for this “B Delay” and thus is plainly incorrect.

Patentees previously filed an application for patent term adjustment prior to payment of the issue fee to address the issue in this section, but the application was

² No request for early processing under 35 U.S.C. § 371(f) was filed for the present application.

dismissed as being “premature” because the patent had yet to issue. The PTO’s position is that its errors in calculating “B Delay” must be raised under 37 C.F.R. § 1.705(d) after issuance of the patent.

IV. THE PTO MISCALCULATED "APPLICANT DELAY" TO THE DETRIMENT OF THE PATENTEES

Patentees contest the PTO’s calculation of Applicant delay of 144 days. The PTO calculation alleges **120 days** of Applicant Delay between January 15, 2009 and June 16, 2009. It appears from the Image File Wrapper (“IFW”) on the Patent Application Information Retrieval (“PAIR”) service that the event that ended this alleged Applicant Delay was entry of drawing sheets on June 16, 2009.

The undersigned agent has reviewed the PTO’s records on PAIR and file records of Patentees’ representatives at Marshall, Gerstein & Borun (“MGB”) and find no Patentees’ activities that justify a finding of 120 days of delay. Patentees’ amendment entered January 23, 2008 was filed by a Final Office Action mailed March 10, 2009. The Final Office Action was followed by a submission by the Patentees on April 27, 2009, which was followed by a Notice of Allowance issued by the PTO on May 8, 2009. The issue fee was timely paid thereafter.

The drawing entry on June 16, 2009 in the IFW appears to be a copy of original PCT Figures and was not submitted by the Patentees on June 16, 2009.

MGB routinely maintain paper copies of patent application files. After a review of the paper file for this application, no records of the submission of a drawing on June 16, 2009 was found. After a review of PAIR, Patentees determined that the drawing referred to by the Patent Office was not submitted by the Patentees. No such drawing was filed by the Patentees with the PTO after the Notice of Allowance and, therefore, the Patentee should not have accrued such a delay.

Patentees could not have disputed the 120 days of Applicant Delay under 37 C.F.R. § 1.705(b) prior to payment of the issue fee because Patentees were not aware that such a delay was being alleged. Attached as Exhibit A is a copy of the PTO’s patent term adjustment calculation for this application that was printed from PAIR on August 5, 2009 (prior to the filing of the application for patent term adjustment filed on August 6, 2009 and also prior to payment of the issue fee). The PTA calculation

shows no activity after the mailing of the Notice of Allowance, and specifically no alleged 120 day Applicant Delay that is now alleged.

Patentees do not dispute, for purposes of this request, the PTO's calculation of 24 days constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704. (24 days due to extension of time, November 29 to December 23, 2008). (See PTO's calculation.) The total Applicant Delay should be 24 days.

V. OVERLAP OF "A DELAY" AND "B DELAY"

As detailed in the PTO's calculations, 33 days of "A Delay" accumulated before May 23, 2008 and 36 6 days accumulated after August 7, 2009..

As detailed above, "B Delay" accumulated after June 10, 2009.

According to Patentees' calculations, 36 days of "A Delay" occurred during the overlap period (June 11, 2009 through January 12, 2010) and should be subtracted from the PTA due to applicant according to 35 U.S.C. §154(b)(2)(A).

VI. TERMINAL DISCLAIMER

This patent is not subject to a terminal disclaimer.

VII. CONCLUSION – CORRECT PATENT TERM ADJUSTMENT

Total PTA should be calculated as follows:

$[A \text{ delay} + B \text{ delay}] - \text{Overlap} - \text{Applicant delay} = \text{PTA}$

wherein:

A delay is 69 days,

B delay is 216 days as explained in section III,

The Overlap between the A and B delay is 36 days as explained in section IV, and the Applicant delay is 24 days as explained in section II(B).

According to this calculation, the PTA properly due to the Patentees is 225 days $([69 + 216] - 36 - 24 = 225 \text{ days})$.

The fee of \$200.00 required under 37 C.F.R § 1.18(e) has been paid by credit card. The Director is hereby authorized to charge any deficiency in the fees filed,

asserted to be filed, or which should have been filed herewith to our Deposit Account No. 13-2855, under Order No. 31265/5868A.

Dated: February 16, 2010

Respectfully submitted,

By: /Jeanne M. Brashear/56,301

Jeanne M. Brashear

Registration No.: 56,301

MARSHALL, GERSTEIN & BORUN LLP

233 S. Wacker Drive, Suite 6300

Sears Tower

Chicago, Illinois 60606-6357

(312) 474-6300

Agent for Patentees

EXHIBIT A



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10/582,316

TUMOUR SUPPRESSOR PROTEIN

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Patent Term Adjustment

Filing or 371(c) Date:	02-20-2007	USPTO Delay (PTO) Delay (days):	33
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	24
Post-Issue Petitions (days):	+0	Total Patent Term Adjustment (days):	9
USPTO Adjustment (days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
05-08-2009	Mail Notice of Allowance		
05-07-2009	Document Verification		
05-05-2009	Notice of Allowance Data Verification Completed		
05-05-2009	Case Docketed to Examiner in GAU		
05-05-2009	Examiner's Amendment Communication		
04-28-2009	Examiner Interview Summary Record (PTOL - 413)		
04-27-2009	Oath or Declaration Filed (Including Supplemental)		
03-11-2009	Mail Final Rejection (PTOL - 326)		
03-10-2009	Final Rejection		
01-15-2009	Date Forwarded to Examiner		
12-23-2008	Response after Non-Final Action		
12-23-2008	Request for Extension of Time - Granted		24
08-29-2008	Mail Non-Final Rejection		↑
08-28-2008	Non-Final Rejection		↑
07-05-2008	Date Forwarded to Examiner		
06-23-2008	Response to Election / Restriction Filed		
05-23-2008	Mail Restriction Requirement	33	
05-22-2008	Requirement for Restriction / Election	↑	
01-25-2008	Change in Power of Attorney (May Include Associate POA)	↑	
01-22-2008	Correspondence Address Change	↑	
10-30-2007	Case Docketed to Examiner in GAU	↑	
06-07-2007	PG-Pub Issue Notification	↑	
03-27-2007	Case Docketed to Examiner in GAU	↑	
03-06-2007	IFW TSS Processing by Tech Center Complete	↑	
02-20-2007	371 Completion Date	↑	
03-02-2007	Application Dispatched from OIPE		
03-02-2007	Notice of DO/EO Acceptance Mailed		
02-20-2007	Additional Application Filing Fees		
02-20-2007	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant		

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- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail EBCC@uspto.gov for specific questions about Patent Application Information Retrieval (PAIR).
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